

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Buiser et al.
Serial No. : 10/830,195
Filed : April 22, 2004
Title : EMBOLIZATION

Art Unit : 1618
Examiner : Leah H. Schlientz
Conf. No. : 7713

Mail Stop Appeal Brief - Patents

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

BRIEF ON APPEAL

(1) Real Party in Interest

Boston Scientific Scimed, Inc.

(2) Related Appeals and Interferences

None.

(3) Status of Claims

Claims 1-4, 11, 23-31, 49-53, 60, 62 and 63 are pending. Claims 5-10, 12-22, 32-48, 54-59 and 61 are cancelled.

Claims 1-4, 11, 23-31, 49-53, 60, 62 and 63 are under final rejection.

(4) Status of Amendments

All amendments have been entered.

(5) Summary of Claimed Subject Matter

Claim 1 is the only independent claim.

Claim 1 is directed to compositions that include a particle chain having at least two connected particles and a link that connects the at least two connected particles. *See* U.S.S.N. 10/830,195, p. 1, lines 9-10. The at least two connected particles and the link are integrally formed of PVA. *See id.*, p. 3, line 13 and p. 4, line 4. At least one of the at least two connected

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particles has an interior region with pores having a first mean size, a surface region with pores having a second mean size, and a body region between the interior region and the surface region. *See id.*, p. 12, line 9-p. 13, line 9 and Fig. 5. The body region includes pores with a third mean size, where the third mean size is greater than the second mean size. *See id.* The first mean size is about 20 microns or more. *See id.* The second mean size is about one micron or less. *See id.* The third mean size is about 18 microns or less. *See id.* The link has an aspect ratio of at most about 1,000 and the link has an aspect ratio of at least about 0.001. *See id.*, p. 3, lines 4-5. The ratio of the diameter of one of the at least two particles to a width of the link is at least about 0.5 and the ratio of the diameter of one of the at least two particles to a width of the link is at most about 100. *See id.*, lines 6-8. The link has a length of at least about one micron and wherein the link has a length of at most about 50,000 microns. *See id.*, p. 2, lines 26-30. The link has a width of at most about 0.01 inch and the link has a width of at least 0.001 inch. *See id.*, p. 3, lines 1-3.

(6) Grounds of Rejection to be Reviewed on Appeal

The Examiner rejected claims 1-4, 11, 23-31, 49-53, 60, 62 and 63 under 35 U.S.C. §103(a) as being unpatentable over Jacobsen et al., U.S. Patent No. 6,530,934 ("Jacobsen") and Greene, U.S. 2002/0177855 ("Greene") in view of Lanphere et al., U.S. 2003/0185895 ("Lanphere").

The Examiner rejected claims 1-4, 11, 23-31, 49-53, 60, 62 and 63 under nonstatutory obviousness-type double patenting as being unpatentable over U.S. Patents No. 7,131,997; 7,449,236; 7,462,366; 7,588,780; and 7,611,542 in view of Jacobsen and Greene.

The Examiner provisionally rejected claims 1-4, 11, 23-31, 49-53, 60, 62 and 63 under nonstatutory obviousness-type double patenting as being unpatentable over U.S.S.N. 12/235,978; 12/236,051; and 10/651,475 in view of Jacobsen and Greene

(7) Argument

The Rejection under 35 U.S.C. §103(a)

The Examiner rejected claims 1-4, 11, 23-31, 49-53, 60, 62 and 63 under 35 U.S.C. §103(a) as being unpatentable over Jacobsen and Green in view of Lanphere. Appellant does not

concede that it would have been obvious to try to combine the references in the manner indicated by the Examiner. Nonetheless, assuming solely for the sake of discussion, that it would have been obvious to one skilled in the art to try to combine the references in the manner indicated by the Examiner, the Examiner has failed to demonstrate how the references could have been combined. Thus, the obviousness rejection is improper because the Examiner has not demonstrated that the asserted combination of Jacobsen, Greene and Lanphere would have enabled one skilled in the art to make the subject matter covered by the claims.

Applicable caselaw clearly states that “[i]n order to render a claimed apparatus or method obvious, the prior art must enable one skilled in the art to make and use the apparatus or method.” *Beakman Instruments, Inc. v. LKB Produkter AB*, 892 F2d 1547, 1551, 13 USPQ2d 1301, 1304 (Fed. Cir. 1989). A claim rejection for obviousness under 35 USC §103 is improper if a person skilled in the art would not be able to make a claimed composition or perform a claimed method upon reviewing the cited prior art without undue experimentation:

[r]eferences relied upon to support a rejection under 35 USC 103 must provide an enabling disclosure, i.e., they must place the claimed invention in the possession of the public. [citations omitted] An invention is not ‘possessed’ absent some known or obvious way to make it.” *In re Payne, Durden and Weiden*, 606 F2d 303, 314, 203 USPQ 245, 255 (CCPA 1979).

Under this standard, an obviousness rejection under 35 USC §103 of a composition claim is improper in “the absence of a known or obvious process for making the claimed compounds.” *In re Hoeksema*, 399 F2d 209, 274, 158 USPQ 596, 601 (CCPA 1968).

Each individual prior art reference is only presumed to be operable when it individually “expressly anticipates or makes obvious all of the elements of the claimed invention, the reference is presumed to be operable” *See* MPEP §2121 (emphasis added). This presumption does not extend to a combination of references that requires modification of the references as a basis for an obviousness rejection. Thus, given that the Examiner has conceded that none of the references relied upon by the Examiner individually discloses the subject matter covered by Appellant’s claims, the asserted combination and modification of Jacobsen, Greene and

Lanphere is not presumed to enable one skilled in the art to make the purported result of the combination/modification.

It is important for the Examiner to understand that Appellant is not arguing that the references are not physically combinable (although Appellant is not conceding that the references are physically combinable). Rather, Appellant is arguing that the references do not teach one skilled in the art to make the subject matter that the Examiner alleges would result from combining the references. Hence, Appellant believes that the portions of MPEP §2145, as well as *In re Keller* and *In re Sneed*, previously cited by the Examiner are not relevant.

Fundamentally, the Examiner has to establish that, based on the references relied upon by the Examiner, one skilled in the art would have been enabled to make the subject matter covered by the claims. The Examiner has not done this.

Neither Jacoben nor Lanphere even disclose a process for joining particles, and therefore it cannot be properly asserted that Jacobsen and/or Lanphere enable Appellant's claimed subject matter. The mere fact that each of these references individually discloses porous particles does not change this conclusion. Similarly, the mere fact that Jacobsen discloses that, for the particular materials he discloses, links and particles could be made of the same material, does not change the conclusion where Appellant's claims cover different particles and links and Jacobsen is silent regarding the manner in which he allegedly made his disclosed subject matter.¹ In addition, the processes disclosed by Greene would not work for Appellant's claimed subject matter, at least because the claimed subject matter requires the link and the at least particles to be integrally formed of the same material. As a result, none of the references relied upon by the Examiner, alone or in the Examiner's proposed combination, enable one skilled in the art to make the subject matter covered by Appellant's claims.

Accordingly, it would not have been obvious to one skilled in the art to combine the references in the manner indicated by the Examiner to provide the subject matter covered by Appellant's claims. Thus, Appellant requests reconsideration and reversal of the rejection under 35 U.S.C. §103(a).

¹ Appellant does not concede that, under circumstances where an issued patent discloses subject matter without disclosing how such subject matter is made, it is appropriate to conclude that the reference enables one skilled in the art to make the subject matter.

The Obviousness-Type Double Patenting Rejections

The Examiner rejected claims 1-4, 11, 23-31, 49-53, 60, 62 and 63 under nonstatutory obviousness-type double patenting as being unpatentable over U.S. Patents No. 7,131,997; 7,449,236; 7,462,366; 7,588,780; and 7,611,542 in view of Jacobsen and Greene.

In addition, the Examiner provisionally rejected claims 1-4, 11, 23-31, 49-53, 60, 62 and 63 under nonstatutory obviousness-type double patenting as being unpatentable over U.S.S.N. 12/235,978; 12/236,051; and 10/651,475 in view of Jacobsen and Greene.

Appellant request reconsideration and reversal of each of the obviousness-type double patenting rejections in view of the arguments presented in the preceding section.

Please apply the brief fee of \$540, and any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: July 20, 2010

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Appendix of Claims

1. (Previously Presented) A composition, comprising:
a particle chain having at least two connected particles and a link that connects the
at least two connected particles, wherein:
the at least two connected particles and the link are integrally formed of
PVA;
at least one of the at least two connected particles has an interior region
with pores having a first mean size, a surface region with pores having a second mean size, and a
body region between the interior region and the surface region, the body region with pores
having a third mean size, the third mean size being greater than the second mean size,
the first mean size is about 20 microns or more;
the second mean size is about one micron or less;
the third mean size is about 18 microns or less;
the link has an aspect ratio of at most about 1,000 and the link has an
aspect ratio of at least about 0.001;
a ratio of the diameter of one of the at least two particles to a width of the
link is at least about 0.5 and the ratio of the diameter of one of the at least two particles to a
width of the link is at most about 100;
the link has a length of at least about one micron and wherein the link has
a length of at most about 50,000 microns; and
the link has a width of at most about 0.01 inch and the link has a width of
at least 0.001 inch.
2. (Original) The composition of claim 1, wherein each of the at least two connected
particles has a diameter of from about ten microns to about 3,000 microns.
3. (Original) The composition of claim 1, wherein the particle chain has a restrained
length of at most about 50 centimeters.

4. (Original) The composition of claim 1, wherein the particle chain has a restrained length of at least about one centimeter.

5-10. (Cancelled)

11. (Previously Presented) The composition of claim 1, wherein the link has an aspect ratio of at most 25.

12-22. (Cancelled).

23. (Original) The composition of claim 1, wherein the at least two connected particles comprise first and second particles, and a diameter of the first particle is the same as a diameter of the second particle.

24. (Original) The composition of claim 1, wherein the at least two connected particles comprise first and second particles, and a diameter of the first particle is different from a diameter of the second particle.

25. (Previously Presented) The composition of claim 1, wherein the composition further comprises a carrier fluid, and the particle chain is in the carrier fluid.

26. (Original) The composition of claim 25, wherein the carrier fluid comprises a saline solution.

27. (Original) The composition of claim 25, wherein the carrier fluid comprises a contrast agent.

28. (Original) The composition of claim 25, wherein the at least two connected particles have an arithmetic mean diameter of about 3,000 microns or less.

29. (Original) The composition of claim 25, wherein the at least two connected particles have an arithmetic mean diameter of about ten microns or more.

30. (Original) The composition of claim 1, wherein the particle chain has a two-dimensional structure.

31. (Original) The composition of claim 1, wherein the particle chain has a three-dimensional structure.

32-48. (Cancelled).

49. (Previously Presented) The composition of claim 1, wherein the link has a length of at least about 500 microns.

50. (Previously Presented) The composition of claim 1, wherein the link has a length of at least about 1,000 microns.

51. (Previously Presented) The composition of claim 1, wherein the link has a length of at least about 5,000 microns.

52. (Previously Presented) The composition of claim 1, wherein the link has a length of at least about 10,000 microns.

53. (Previously Presented) The composition of claim 1, wherein the link has a length of at least about 30,000 microns.

54-59. (Cancelled).

60. (Previously Presented) The composition of claim 1, further comprising a particle chain complex comprising the first particle attached to two or more particle chains.

61. (Cancelled).

62. (Previously Presented) The composition of claim 61, wherein PVA comprises cross-linked PVA.

63. (Previously Presented) The composition of claim 62, wherein the first particle has a sphericity of about 0.9 or more.

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Evidence Appendix

None.

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Related Proceedings Appendix

None.